International Journal of Current Research and Review
DOI: 10.7324/IJCRR.2018.1071

Research Article

IJCRR
Section: Healthcare
Sci. Journal Impact Factor: 5.385 (2017)
ICV: 71.54 (2015)

A Study of Haemoglobin Level based on Tenofovir given as a First Line Anti Retroviral Therapy in Human Immune Virus Infected Patient

Kapildev Mondal[1], Soumabrota Dutta[2]

[1]Assistant Professor, Department of General Medicine, Murshidabad Medical College & Hospital, Westbengal, India; [2]R.M.O cum Clinical Tutor, Department of Radiology, Murshidabad Medical College & Hospital, Westbengal, India.

ABSTRACT

Background: Tenofovir has been recently introduced in our country as first line therapy in HIV infection but limited data available on safety profile & tolerability in Indian population of patients. This study focused on change of haemoglobin level due toTenofovir given as a first line anti retroviral therapy in HIV infected patient.

Aims of the Study: To show the change of haemoglobin level due to tenofovir in tenofovir based first line anti retroviral therapy in HIV infected patient.

Materials & Methods: We studied descriptive & longitudinal study in Art center in Murshidabad medical College & hospital, west Bengal, July 2014 to June 2015.Our study included 107 HIV infected patient (aged 18 years and above) attending Art center, Murshidabad medical College & Hospital who will be started on Tenofovir based 1st line Art (according to NACO guideline) except Pregnant women, patients with serum creatinine >1.2mg/dl & unwilling for consent.

Discussion: During this period 10 of them left the study due to lack of follow up. The study population had overall weight gained & increased by haemoglobin at the end of the study.

Results: This study shows that tenofovir is well tolerable drug. Tenofovir therapy is associated with mean weight gain and increase in haemoglobin level.

Conclusion: Tenofovir therapy is associated with mean weight gain and increase in haemoglobin level.

Key Words: Weight, Mean, Creatinine

INTRODUCTION

Tenofovir recently use in our country as first line therapy in HIV infection but limited data available on safety profile in Indian. The study will focus on change of haemoglobin level due to tenofovir based first line anti retroviral therapy in human immune virus infected patient.

METHODS

We did approval from Institutional ethics committee & Informed consent from all the study subjects. We studied subjects from July 2014 to June 2015 and followed up upto12 months. We took detailed history & did physical examinations and baseline investigation before initiation of Art and subsequently at 2 weeks, 1 month, 3 months , 6 months & 12 months of starting of Art. We assessed haemoglobin level before initiation, after 12 months of Art theraphy and different laboratory tests report. We collected all data & analyzed by using SPSS.

RESULTS

This study shows that tenofovir is well tolerated drug in this population of patients with once daily regimen which has

Corresponding Author:
Kapildev Mondal, Assistant Professor, Department of General Medicine, Murshidabad Medical College & Hospital, Westbengal, India
Mob: 08697910070, Email: kapilmondal980@gmail.com

ISSN: 2231-2196 (Print) **ISSN:** 0975-5241 (Online)
Received: 16.08.2017 **Revised:** 03.10.2017 **Accepted:** 18.11.2017

improved patients compliance. Tenofovir therapy improves overall general health of the patients. Tenofovir therapy is associated with mean weight gain and increased in haemoglobin level. It is not associated with adverse effect on total leucocyte count, differential leucocyte count, platelet count, serum bilirubin and serum liver enzymes (SGOT, SGPT).

DISCUSSION

HIV infection causes significant morbidity and mortality by causing an immune deficient state and patients usually succumb to death from unusual opportunistic infections and malignancies. However HIV infection is a manageable HAART. We conducted the study involving 107 eligible patients who were followed up for a period of 12 months. During followed up period of 12 months ten of them left the study. We studied the effect of tenofovir on haemoglobin level on that period.

We observed gastrointestinal intolerance which includes anorexia, nausea, vomiting and upper abdominal pain in 12.37% patients at 2 weeks of starting of ART which subsequently relieved with time. Only 4% patients had GI intolerance at 1 month which relieved after few days. We found that there is increment in mean haemoglobin level of total study population from base line value. There was no effect on the total and differential leucocyte count or on the mean platelet count.

We found no adverse effect of the drug on liver function (serum bilirubin, SGOT, SGPT did not show any change).

The study showed that there is increasing value of mean serum creatinine level of total study population from base line value but mean serum creatinine at the end of study remained within normal reference value. None of the study population developed acute renal failure or feature of proximal renal tubular dysfunction (glycosuria in presence of normal plasma glucose and proteinurea) for which discontinuation of tenofovir required. The pattern of change in serum creatinine level is same in both sex groups.

We also found that there was increasing value of mean serum urea level of the total study population from base line value although the value at the end of study remained within normal reference value.

We found there is clinical & biochemical improvement of overall health in general study of the population probably due to well control of the disease and also the control of opportunistic infection. The study population had overall weight gain at the end of the study

Conclusion: Tenofovir increases the level of haemoglobin on that period. This study result reveals improvement of haemoglobin level based on tenofovir given as a first line anti retroviral therapy in human immune virus infected patient.

Ethical Considerations: The Institutional Ethics Committee of Murshidabad medical college & hospital approved of our study.

ACKNOWLEDGEMENT

We are grateful and indebted to respected Principal Sir, MSVP Sir, Deputy Superintendent and Assistant Superintendents for being of help whenever needed.

Source of fund: We use from our personal account.

Interest of study: There is no conflict of interest for the study.

ABBREVIATION

TDF-Tenofovir disoproxil fumarate.

NACO-National Aids control organization.

ART-Antiretroviral therapy.

PrEP-Pre-exposure prophylaxis.

Sd- Standard deviation.

Hb-Haemoglobin.

TLC-Total leucocyte count.

DLC-Differential leucocyte count.

LFT-Liver function test.

ALT-Alanine transaminase.

HIV- Human Immunodeficiency Virus.

SIV- Simian Immunodeficiency Virus.

AIDS- Acquired Immunodeficiency Syndrome.

AZT –Zidovudine.

HAART- Highly active antiretroviral therapy.

NNRTI -Non-nucleoside reverse trancriptase inhibitor.

REFERENCES

1. Cooper D Ryan, Wiebe Natasha et al. Systematic Review and Meta-analysis: Renal Safety of Tenofovir Disoproxil Fumarate in HIV- Infected Patients. Clin Infect Dis. 2010;51(5):496-505.
2. Bygrave Helen, Ford Nathan, Cutsem van Gilles et al. Implementing a Tenofovir-Based First- Regimen in Rural Lesotho: Clinical Outcomes and Toxicities After Two Years. J Acquir Immune Defic Syndr 2011;56:75–8.
3. Phair J, Palella F. Renal disease in HIV-infected individuals.**Curr Opin HIV AIDS. 2011**Jul;6(4):285-9.
4. Fernando SK, Finkelstein FO, Moore BA, Weissman S. Prevalence of chronic kidney disease in an urban HIV infected population. Am J Med Sci. 2008;335:89–94.

5. Hall AM, Hendry BM, Nitsch D, Connolly JO. Tenofovir-Associated Kidney Toxicity in HIV-Infected Patients: A Review of the Evidence. Am J Kidney Dis. 2011;57:773–80.
6. Horberg M, Tang B, Towner W, Silverberg M, Bersoff-Matcha S, Hurley L, et al. Impact of tenofovir on renal function in HIV infected, antiretroviral-naive patients. J Acquir Immune Defic Syndr. 2010;53:62–69.
7. Calza L, Trapani F, Tedeschi S, Piergentili B, Manfredi R, Colangeli V, et al. Tenofovir-induced renal toxicity in 324 HIV-infected, antiretroviral-naive patients. Scand J Infect Dis 2011Aug;43(8):656-60.
8. Martinez E, Arranz JA, Podzamczer D, Lonca M, Sanz J, Barragan P,et al. A simplification trial switching from nucleoside reverse transcriptase inhibitors to once-daily fixed-dose abacavir/lamivudine or tenofovir/emtricitabine in HIV-1-infected patients with virological suppression. J Acquir Immune Defic Syndr. 2009;51:290–97.
9. Longenecker CT, Scherzer R, Bacchetti P, Lewis CE, Grunfeld C, Shlipak MG. HIV viremia and changes in kidney function. Aids 2009;23:1089–96.
10. Ando M, Yanagisawa N, Ajisawa A, Tsuchiya K, Nitta K. Kidney tubular damage in the absence of glomerular defects in HIV infected patients on highly active antiretroviral therapy. 2011 Oct;26(10):3224-9.
11. Rebecca Scherzer, Michelle Estrella, Yongmei Li, Steven G. Deeks, Carl Grunfeld and Michael G. Shlipak. Association of tenofovir exposure with kidney disease risk in HIV infection. AIDS2012 Apr 24;26(7):867-75.
12. Woodward CL, Hall AM, Wiliums IG, Madge S, Copas A, Nair D, et al. Tenofovir associated renal and bone toxicity. HIV Med 2009;10:482-7.
13. Weber R, Sabin CA, Friis-Møller N, Reiss P, El-Sadr WM, Kirk O, Dabis F, Law MG, Pradier C, De Wit S, Akerlund B, Calvo G, Monforte Ad, Rickenbach M, Ledergerber B, Phillips AN, Lundgren JD. Liver-related deaths in persons infected with the human immunodeficiency virus: the D:A:D study. Arch Intern Med 2006;166:1632-41.
14. Alter MJ. Epidemiology of viral hepatitis and HIV co-infection. J Hepatol 2006;44:6-9.
15. SorianoV, Puoti M, Peters M, Benhamou Y, Sulkowski M, Zoulim F, Mauss S, Rockstroh J. Care of HIV patients with chronic hepatitis B: updated recommendations from the HIV Hepatitis B Virus International Panel. AIDS2008; 22: 1399-1410.
16. Tenney DJ, Rose RE, Baldick CJ, Pokornowski KA, Eggers BJ, Fang J, Wichroski MJ, Xu D, Yang J, Wilber RB, Colonno RJ. Long-term monitoring shows hepatitis B virus resistance to entecavir in nucleoside-naïve patients is rare through 5 years of therapy. Hepatology 2009;49:1503-14.
17. Price H, Dunn D, Pillay D, Bani-Sadr F, de Vries-Sluijs T, Jain MK, Kuzushita N, Mauss S, Núñez M, Nüesch R, Peters M, Reiberger T, Stephan C, Tan L, Gilson R. Suppression of HBV by tenofovir in HBV/HIV co-infected patients: a systematic review and meta-analysis. PLoS One 2013; 8: e68152.[PMID: 23874527 DOI: 10.1371/journal.pone.0068152]
18. Kitrinos KM, Corsa A, Liu Y, Flaherty J, Snow-Lampart A, Marcellin P, Borroto-Esoda K, Miller MD. No detectable resistance to tenofovir disoproxil fumarate after 6 years of therapy in patients with chronic hepatitis B. Hepatology 2014; 59: 434-42.
19. Rockstroh JK, Bhagani S, Benhamou Y, Bruno R, Mauss S, Peters L, Puoti M, Soriano V, Tural C. European AIDS Clinical Society (EACS) guidelines for the clinical management and treatment of chronic hepatitis B and C coinfection in HIV-infected adults. HIV Med 2008;9:82-88.
20. Brook G, Main J, Nelson M, Bhagani S, Wilkins E, Leen C, et al. British HIV Association guidelines for the management of coinfection with HIV-1 and hepatitis B or C virus 2010. HIV Med 2010;11:1-30.
21. Soriano V, Tuma P, Vispo E, Labarga P, Fernández JV, Medrano J, Barreiro P. Hepatitis B in HIV patients: what is the current treatment and what are the challenges? J HIV Ther 2009;14:13-18.
22. Benhamou Y, Fleury H, Trimoulet P, Pellegrin I, Urbinelli R, Katlama C, et al. Anti-hepatitis B virus efficacy of tenofovir disoproxil fumarate in HIV-infected patients. Hepatology 2006;43:548-55.
23. Zoutendijk R, Zaaijer HL, de Vries-Sluijs TE, Reijnders JG, Mulder JW, Kroon FP, et al. Hepatitis B surface antigen declines and clearance during long-term tenofovir therapy in patients coinfected with HBV and HIV. J Infect Dis 2012;206:974-80.
24. Phung BC, Sogni P, Launay O. Hepatitis B and human immunodeficiency virus co-infection. World J Gastroenterol 2014; 20(46): 17360-67.
25. Nelson M, Portsmouth S, Stebbing J, Atkins M, Barr A, Matthews G, et al. An open-label study of tenofovir in HIV-1and hepatitis B virus co-infected individuals. AIDS 2003;17:F7–F10.
26. Kourtis AP, Bulterys M, Hu DJ, Jamieson DJ. HIV- HBV-a global challenge. N Engl J Med.2012;366:1749-52.
27. Matthews GV, Avihingsanon A, Lewin SR, Amin J, Rerknimitr R, et al. A randomized trial of combination hepatitis B therapy in HIV/HBV coinfected antiretroviral naïve individuals in Thailand. Hepatology 2008;48:1062-69.
28. McColl DJ, Margot NA, Wulfsohn M, et al. Patterns of resistance emerging in HIV-1 from antiretroviral-experienced patients undergoing intensification therapy with tenofovir disoproxil fumarate. J Acquir Immune Defic Syndr 2004;37:1340-50.
29. Miller MD, Margot N, Lu B, Zhong L, Chen S-S, Cheng A, et al. Genotypic and phenotypic predictors of the magnitude of response to tenofovir disoproxil fumarate treatment in antiretroviral-experienced patients. J Infect Dis 2004;189: 837-46.
30. Miller MD, Margot NA, Hertogs K, Larder B, Miller V. Antiviral activity of tenofovir (PMPA) against nucleoside-resistant clinical HIV samples. Nucleosides Nucleotides Nucleic Acids.2001;20:1025–28.
31. Margot NA, Isaacson E, McGowan I, Cheng A, Miller MD. Extended treatment with tenofovir disoproxil fumarate in treatment-experienced HIV-1-infected patients: genotypic, phenotypic, and rebound analyses. J Acquir immune Defic Syndr. 2003;33:15-21.
32. Wainberg MA, Miller MD, Quan Y, Salomon H, Mulato AS, Lamy PD, et al. In vitro selection and characterization of HIV-1 with reduced susceptibility to PMPA. Antivir Ther1999;4:87–94.
33. Larder BA, Stammers DK. Closing in on HIV drug resistance. Nat Struct Biol 1999;6:103–106.
34. Boyer PL, Sarafianos SG, Arnold E, Hughes SH. Selective excision of AZTMP by drug-resistant human immunodeficiency virus reverse transcriptase. J Virol 2001;75:4832–42.
35. Kellam P, Boucher CA, Larder BA. Fifth mutation in human immunodeficiency virus type 1 reverse transcriptase contributes to the development of high-level resistance to zidovudine. Proc Natl Acad Sci USA 1992;89:1934–38.
36. Wainberg MA, White AJ. Current insights into reverse transcriptase inhibitor-associated resistance. Antivir Ther 2001;6(2):11–19.
37. Santiago ML, Range F, Keele BF, Li Y, Bailes E, Bibollet-Ruche F, et al. Simian immunodeficiency virus infection in free-ranging sooty mangabeys (Cercocebus atys atys) from the Tai Forest,

Cote d'Ivoire: Implications for the origin of epidemic human immunodeficiency virus type 2. J Virol.2005;79:12515–27.
38. Stone VE. Strategies for optimizing adherence to highly active antiretroviral therapy: lessons from research and clinical practice. Clin Infect Dis. 200115;33:865–72.
39. Ford N, Calmy A. Improving first-line antiretroviral therapy in resource limited settings. Current Opin HIV AIDS.2010;5:38–47.
40. Brinkman K. Stavudine in antiretroviral therapy: is this the end? AIDS.2009; 23: 1727–29.
41. Gallant JE, DeJesus E, Arribas JR, et al. Tenofovir DF, Emtricitabine, and efavirenz vs. zidovudine, lamivudine, and efavirenz for HIV. N Engl J Med. 2006;354:251–60.

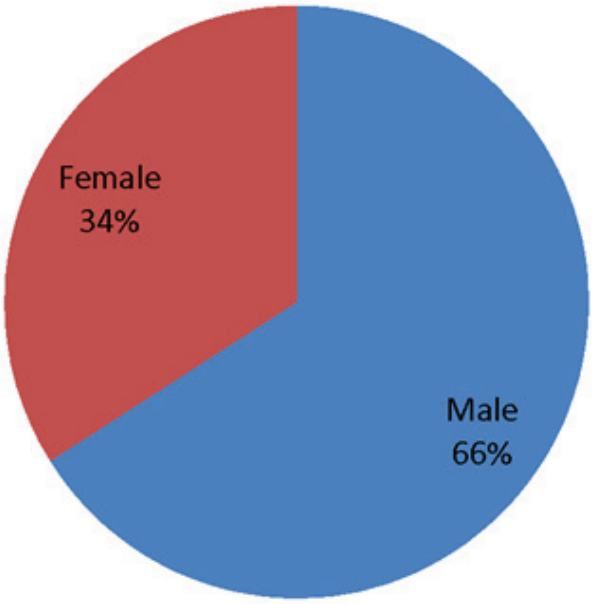

Diagram: Distribution of total population according to sex distribution.

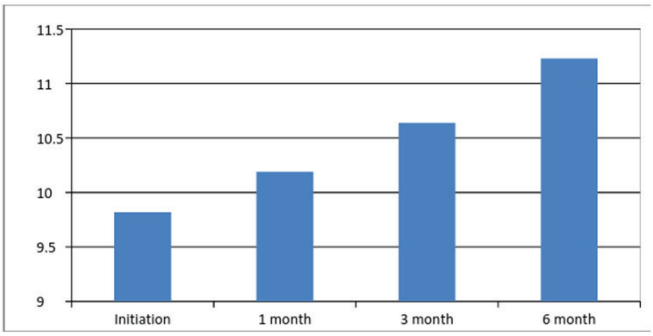

Figure 1: Changes in haemoglobin level (mean+/-Sd) of population under study observed during study period.

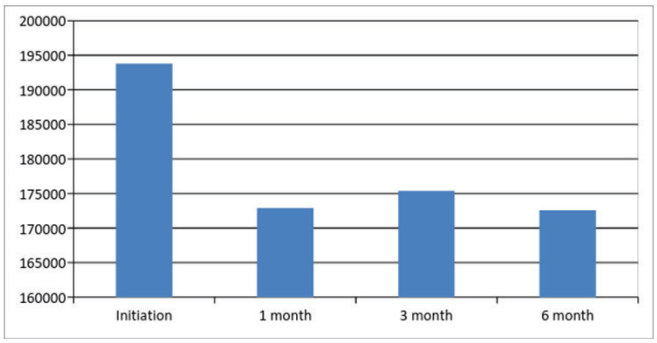

Figure 2: Change in platelet count (mean+/-Sd) of total study population observed during the study period.

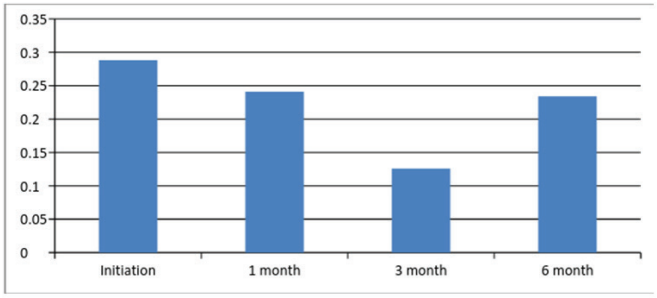

Figure 3: Change in serum direct bilirubin level (mean+/-Sd) of total study population observed during the study period.